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8	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA		
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11	, Individually and on behalf of all	No.	
12	others similarly situated,	CLASS ACTION COMPLAINT	
13	Plaintiff,	FOR VIOLATIONS OF THE	
14	V.	FEDERAL SECURITIES LAWS	
15		CLASS ACTION	
16	TANDEM DIABETES CARE, INC., JOHN F. SHERIDAN, LEIGH A.	JURY TRIAL DEMANDED	
17	VOSSELLER, and SUSAN M.	JORT TRIVE DEIVING VIDED	
18	MORRISON,		
19	Defendants.		
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Plaintiff \_\_\_\_ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, public filings, wire and press releases published by and regarding Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.<sup>1</sup>

#### NATURE OF THE ACTION

- 1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Tandem securities between April 1, 2024, and August 7, 2025, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").
- 2. Tandem is a U.S. medical device company that designs, manufactures, and sells insulin pumps and related diabetes-management technologies. The t:slim X2 is the flagship insulin pump produced by Tandem.
- 3. Defendants provided investors with material information concerning Tandem's t:slim X2 insulin pump. Defendants' statements included, among other things, that Tandem's t:slim X2 insulin pump was safe, reliable, and adequately tested. Defendants failed to timely disclose known safety problems, including the March 2024 battery depletion defect in the t:connect mobile app, which caused

<sup>&</sup>lt;sup>1</sup> Unless otherwise stated, all emphasis is added and internal citations are omitted.

t:slim X2 pumps to shut down prematurely. Defendants also misstated the effectiveness of their post-market surveillance, adverse event reporting, and quality systems. Moreover, Defendants made optimistic guidance and growth statements while concealing, or recklessly failing to disclose, that the t:slim X2's malfunctions and recalls could materially depress sales, increase warranty and recall costs, and impair distribution.

- 4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the reliability of Tandem's t:slim X2 insulin pump was compromised by a systemic battery depletion defect linked to the t:connect mobile app; (2) the effectiveness and efficiency of Tandem's post-market surveillance and quality systems were overstated; (3) the t:connect app and t:slim X2 speaker/software exhibited defects that caused pump shutdowns and rapid battery drain, placing patients at risk; and (4) as a result, Defendants' public statements were materially false and misleading at all relevant times.
- 5. On August 7, 2025, before market hours, Tandem issued a press release announcing a voluntary medical device correction for select t:slim X2 insulin pumps. Therein, the Company reported a speaker-related issue that appears to be a Malfunction 16 alarm to users of Tandem's t:slim X2 insulin pumps. The Company further disclosed that this speaker-related issue can trigger an error resulting in a discontinuation of insulin delivery.
- 6. Following the foregoing press release concerning Tandem's t:slim X2 product, Tandem's common stock fell \$2.87 per share, or 19.9%, to close at \$11.52 per share on August 7, 2025.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **JURISDICTION AND VENUE**

- 8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the Securities Exchange Commission (the "SEC") (17 C.F.R. § 240.10b-5).
- 9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).
- 10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.
- 11. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants (defined below), directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

## **PARTIES**

- 12. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Tandem securities during the Class Period and was economically damaged thereby.
- 13. The Company is incorporated and its principal executive offices are located in San Diego, California. The Company maintains offices in this judicial

- 19. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.
- 20. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Tandem under *respondeat superior* and agency principles.
- 21. Defendant Tandem and the Individual Defendants are collectively referred to herein as "Defendants."

#### **SUBSTANTIVE ALLEGATIONS**

#### **Background**

22. Tandem purports to be "a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers."

## Materially False and Misleading Statements Issued During the Class Period

- 23. The Class Period begins on April 1, 2024, when the Company filed with the SEC a current report on Form 8-K, announcing an event about its Mobi insulin pump, "[o]n March 21, 2024, the U.S. Food and Drug Administration cleared our 510(k) application for our Tandem Mobi insulin pump with an expanded pediatric indication for use in individuals two ears of age and older."
- 24. On March 18, 2024, when the Company initiated a recall with the Food and Drug Administration ("FDA") of its version 2.7 (released February 12, 2024 on the Apple Ios platform) of the t:connect mobile used in conjunction with Tandem's t:slim X2 insulin pump with Control-IQ technology by correction (the "March 2024").

Recall"). The March 2024 Recall did not become public until it was published by the FDA on May 6, 2024.

- 25. The statement in ¶23 was materially false and misleading at the time it was made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the March 2024 Recall.
- 26. On April 9, 2024, the Company filed with the SEC an annual report for the year of 2023 ("2023 Annual Report") on Form 10-K, in the relevant part:

#### **Overview**

• ... Our pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ advanced hybrid closed-loop technology.

The t:slim X2 Insulin Delivery System has been our flagship technology solution. In February 2024, we expanded our pump portfolio with the U.S. launch of Tandem Mobi. Both pumps feature our Control-IQ advanced hybrid closed loop technology, with an automated insulin delivery (AID) feature designed to help increase a user's time in targeted glycemic range. Our t:slim X2 and Tandem Mobi pumps can be used with a variety of infusion sets to offer patients choice in how and where their pump is worn. In addition, they are software updatable from a personal computer and compatible with our web-based data management application.

Our t:slim X2 and Tandem Mobi pumps feature our Control-IQ advanced hybrid closed loop technology. This AID feature is designed to help increase a user's time in targeted glycemic range (70-180 mg/dL), and is used by the majority of our customers worldwide. Control-IQ was the first AID algorithm cleared by the FDA to deliver automatic correction boluses in addition to adjusting basal insulin to help prevent high and low blood sugar. Control-IQ technology offers optional settings for sleep and exercise activities that adjust the algorithm parameters to better match the different physiological needs during these activities. Results from three independent pivotal studies using Control-IQ technology were published in the New England Journal of Medicine in October 2019, August 2020 and March 2023.

As part of our AID systems, we offer pump integration with multiple CGM sensors, which helps provide customizable solutions for people living

with diabetes. The Dexcom G7 sensor is the fourth generation of Dexcom's CGM that we have integrated with our pump technology since 2015. We began offering our t:slim X2 pump integrated with the Dexcom G7 sensor in the United States in December 2023 and outside the United States in January 2024. In addition, in January 2024 we announced that our t:slim X2 insulin pump with Control-IQ technology is the first AID system to integrate with the Abbott FreeStyle Libre 2 Plus sensor. Our extensive experience in CGM integration, and efforts to continue expanding the available CGM sensors integrated with our pump portfolio, represents our commitment to provide customizable solutions to help reduce burden and create new possibilities for people living with diabetes.

27. In the 2023 Annual Report, the Company made the following statements about its t:slim X2's software:

Tandem Device Updater

• This tool allows our pump users to update their pump software quickly and easily from a personal computer. It is PC- and Maccompatible and designed to work with our pumps in a manner similar to software updates on a smartphone. We have used this technology to offer our in-warranty t:slim X2 customers worldwide software updates at no cost.

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. Our Tandem Device Updater (TDU) has allowed our t:slim X2 customers to update their pump software from a personal computer. Tandem Mobi offers the same update capability with wireless, remote updates. This offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. As an example, we recently launched a pump software update through TDU to allow all t:slim X2 pump users in the United States access to integration with two new CGM sensor offerings.

28. In the 2023 Annual Report, the Company made the following statements concerning government regulation over its t:slim X2 product, Control-IQ technology, and post-market surveillance:

## **Government Regulation**

Regulation of Medical Devices in the United States

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Our products are medical devices subject to extensive regulation by the FDA in the United States, corresponding state regulatory authorities and other regulatory bodies in other countries. Each new or significantly modified medical device we seek to commercially distribute in the United States will require either a pre-market notification under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act (FDCA), also referred to as a 510(k) clearance, or approval from the FDA through the premarket approval (PMA) process. We have obtained clearance on multiple devices in both Class II and Class III, including Control IQ, the tslim:X2 and Tandem Mobi.

. . .

There are three Class II categories classified by the FDA for the interoperability of devices as a complete AID system that are intended to help support continued rapid innovation by streamlining the regulatory pathway for integrated products approved by the FDA. In June 2018, our t:slim X2 was the first insulin pump designated by the FDA as compatible with integrated continuous glucose monitoring (iCGM) devices. In February 2019, we received FDA approval of our de novo application to classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as Alternate Controller Enabled Infusion Pumps (ACE pumps). In December 2019, we received FDA approval of our de novo application to classify our Control-IQ technology as the first automated insulin dosing software in a new interoperable automated glycemic controller (iAGC) category that automatically adjusts insulin delivery to a person with type 1 diabetes age 6 and older by connecting to an ACE pump and iCGM. In November 2023, our Control-IQ technology was cleared with additional features for people with type 1 diabetes age 2 and older. In connection with the de novo applications for both the ACE pump and the iAGC category, the FDA established certain special controls that we will need to continue to satisfy. If we are not able to satisfy those special controls, we would be required to seek approval for those products under the traditional PMA submission application, which must be supported by valid scientific evidence typically includes extensive technical, pre-clinical, that manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and efficacy of the device.

. . .

Also, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. We are currently conducting a post-market surveillance study for our t:slim X2 with Control-

IQ technology for users with type 1 diabetes age six and above. We may elect to pursue additional post-market surveillance studies in the future.

29. In the 2023 Annual Report, the Company disclosed that all of its revenue is generated from the sales of its t:slim X2 insulin pumps, in the relevant part:

We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.

We generate nearly all of our revenue from the sale of t:slim X2 insulin pumps and the related insulin cartridges and infusion sets. In addition, we recently launched our Tandem Mobi insulin pump.

. . .

Because we currently rely on sales of our t:slim X2 insulin pump, and expect to rely on sales of our Tandem Mobi insulin pump, and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products) could adversely affect our business, financial condition and operating results. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which could also have the effect of magnifying the negative impact of any of the factors described above.

30. Further, in the 2023 Annual Report, the Company made the following statements about recent developments of its financial condition and results of operations:

## **Recent Developments**

Tandem Diabetes Care Launches Tandem Mobi, the World's Smallest, Durable Automated Insulin Delivery System

In February 2024, we announced the United States commercial launch of our new Tandem Mobi, the world's smallest, durable automated insulin delivery system for people living with diabetes. We have begun taking orders and shipping to eligible customers in the United States.

Integration of t:slim X2 with Abbott's FreeStyle Libre 2 Plus Sensor In January 2024, we announced that the t:slim X2 insulin pump with Control-IQ technology became the first AID system to integrate with

newly available FreeStyle Libre 2 Plus sensor, Abbott's latest CGM technology. Users in the United States are now able to experience the therapeutic benefits of a hybrid closed-loop system that helps predict and prevent high and low blood sugar. Tandem's t:slim X2 insulin pump connects wirelessly to the FreeStyle Libre 2 Plus sensor, which sends automatic glucose readings every minute to the pump.

31. Further, in the 2023 Annual Report, the Company made the following statements concerning product recalls:

If the results of clinical studies or other experience, such as our monitoring or investigation of customer complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of clearance, certification, or approval from regulatory authorities or Notified Bodies, product recalls or seizure, operating restrictions, interruption of production, fines, civil penalties and criminal prosecution which could result in significant legal liability, harm to our reputation, and a decline in our product sales.

Any alleged illness or injury associated with any of our products or product recalls may negatively impact our financial results and business prospects depending on a number of factors, including the scope and seriousness of the problem, degree of publicity, reaction of our customers and healthcare professionals, competitive response, and consumer perceptions generally. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products have caused or carry a risk of causing illness, injury or death could adversely affect our reputation with customers, healthcare professionals, third-party payors, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price. Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof, may have a similar adverse effect on us.

Since our inception we have been audited or inspected by various regulatory authorities and Notified Bodies on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities and Notified Bodies. *In some instances, these audits, inspections and inquiries* 

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result in findings that require us to take corrective actions, which could include changes to our internal policies, procedures or operations, revisions to our product labeling, issuances of customer notifications or the initiation of product recalls, any of which could result in product liability claims and lawsuits. Our failure to appropriately respond to these findings and take corrective action, or to comply with applicable regulations for any other reason, could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil or criminal penalties, injunctions, warning letters, product recalls, operating restrictions, interruption of production, delays in the introduction of products into the market, refusal of the FDA or other regulatory authorities or Notified Bodies to grant future clearances, certification, or approvals, and the suspension or withdrawal of existing clearances, certifications, or approvals by the FDA, other regulatory authorities or Notified Bodies. Any of these sanctions could result in higher than anticipated costs, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results.

- 32. The statements contained in ¶¶26 through 31 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the March 2024 Recall.
- 33. On April 30, 2025, the Company filed with the SEC a current report on Form 8-K. Attached to this Form 8-K was a press release in which the Company stated the following regarding its t:slim X2 product:

## **About Tandem Diabetes Care, Inc.**

• Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ+ advanced hybrid closed-loop technology. Tandem Diabetes Care is headquartered in San Diego, California. For more information, visit tandemdiabetes.com.

- Tandem Diabetes Care, the Tandem logo, Control-IQ, Control-IQ+, Tandem Mobi and t:slim X2 are either registered trademarks or trademarks of Tandem Diabetes Care, Inc. in the United States and/or other countries.
- 34. The statements contained in ¶33 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the March 2024 Recall.
- 35. On May 2, 2024, the Company filed with the SEC a current report on Form 8-K, attached to this Form 8-K is a press released headlined "Tandem Diabetes Care Announces First Quarter 2024 Financial Results and Updates Full Year 2024 Financial Guidance," which the Company mentioned its t:slim X2 insulin pump, in the relevant part:

## First Quarter 2024 Highlights Compared to First Quarter 2023:

- First quarter 2024 commercial launches:
  - Launched Tandem Mobi with Dexcom G6 continuous glucose monitoring (CGM) sensor integration in the United States.
  - Launched t:slim X2 integration with the Abbott Freestyle Libre 2 Plus CGM sensor in the United States.
  - Initiated rolling launch of t:slim X2 with Dexcom G7 sensor integration outside the United States.
- 36. The statements contained in ¶35 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the March 2024 Recall.
- 37. On May 2, 2024, the Company filed with the SEC a quarterly report for the quarter period ended on March 31, 2024 ("1Q2024 Report"). In the 1Q2024 Report, the Company made the following statements about the t:slim X2 insulin pump and its software:

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. Our Tandem Device Updater (TDU) has allowed our t:slim X2 customers to update their pump software from a personal computer. Tandem Mobi offers the same update capability with wireless, remote updates. This offering is a comfpetitive

advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. As an example, we recently launched a pump software update through TDU to allow all t:slim X2 pump users in the United States access to integration with two new CGM sensor offerings.

- 38. Appended to the 1Q2025 Report as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants Sheridan and Vosseller, attesting that "[b]ased on my knowledge, this report [1Q2025 Report] does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."
- 39. The statements contained in ¶¶37 through 38 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the March 2024 Recall.
- 40. On May 6, 2024, the FDA published a Class 1 recall notice, the most severe level of product recall, concerning the Company's t:connect mobile app used in conjunction with the t:slim X2 insulin pump equipped with Control-IQ technology ("May 2024 Recall Notice"), in the relevant part:

Date Initiated by Firm: March 05, 2024

Date Posted: May 06, 2024 Recall Status: Open, Classified

Product: t:connect mobile app used in conjunction with t:slim X2 insulin pump with Control-IQ technology

Manufacturer Reason for Recall: During normal use, the mobile app version 2.7 may crash and be automatically relaunched by the iOS operating system. This cycle intermittently repeats, which leads to excessive Bluetooth communication that may result in pump battery drain and may lead to the pump shutting down sooner than typically expected. Pump shutdown will cause insulin delivery to suspend, which could lead

to an under-delivery of insulin and may result in hyperglycemia, including severe hyperglycemia.

- 41. On May 16, 2024, the Company filed with the SEC a current report on Form 8-K, in the relevant part about the Company's t:slim X2 product:
  - On May 13, 2024, Health Canada approved the addition of Trurapi U-100 to the list of compatible insulins that can be used with the Company's t:slim X2 pump with Control-IQ technology in Canada.
- 42. On August 1, 2024, the Company filed with the SEC a quarterly report on Form 10-Q for the quarter period ended on June 30, 2024 ("2Q2024 Report"), the Company stated, in the relevant part:

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. This has allowed our t:slim X2 and Tandem Mobi customers to update their own pump software. We believe this offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. As an example, we recently launched pump software updates to allow Tandem pump users access to integrate with new CGM sensors.

43. On August 19, 2024, the Company issued a press release headlined "Tandem Diabetes Care to Release Updated iOS t:connect Mobile App for t:slim X2 Insulin Pump Users Impacted by March 2024 Nationwide Recall," where the Company stated, in the relevant part:

Tandem Diabetes Care, Inc. (Nasdaq: TNDM) today announced the planned release of version 2.8.2 of its Apple iOS t:connect mobile app in the United States on August 20, 2024 to correct an issue described in a March 2024 recall that can cause rapid depletion of a user's t:slim X2 insulin pump battery. This battery depletion can result in the pump shutting down sooner than expected, which some customers have continued to see following the release of version 2.7.1 of the app in March. Tandem encourages all impacted t:slim X2 iOS users to update their mobile app as soon as the new version is available in the Apple App Store.

Under-delivery of insulin because of a pump shutdown can result in hyperglycemia or diabetic ketoacidosis, which can be a life-threatening condition due to high blood sugar and lack of insulin. There have been

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143 confirmed adverse events with this recall. Adverse events are defined as a confirmed high blood sugar and/or an event requiring medical intervention. Two hospitalizations and no deaths have been reported.

44. On November 6, 2024, the Company filed with the SEC a quarterly report on Form 10-Q for the quarter period ended on September 30, 2024 ("3Q2024 Report"). The Company made the following statements about its March 2024 recall:

In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third-party service providers or other third parties with whom we work, that could contain vulnerabilities. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work), but we may not be able to detect, mitigate, and remediate such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our risks may increase significantly due to the use of mobile and cloud-based applications in our medical devices. For example, while use of our Tandem Device Updater is designed to give us the ability to quickly recover from certain risks and/or vulnerabilities, the use of mobile applications enables third parties to store their information on mobile devices that we do not control. Vulnerabilities could be exploited and result in a security incident. In addition to vulnerabilities, the reliance of our insulin pumps and other products on software and hardware exposes us and our customers to risks that may impact the performance of our products. For example, in March 2024, we issued a recall of our Apple iOS t:connect mobile app in the United States relating to an issue that could cause rapid depletion of a user's t:slim X2 insulin pump battery (the "March 2024 Recall"). On August 20, 2024, we released an updated version of the impacted app to correct the issue described in the March 2024 recall.

45. On February 26, the Company filed with the SEC an annual report on Form 10-K for the fiscal year ended December 31, 2024 ("2024 Annual Report"). In the 2024 Annual Report, the Company made the following general statements about its t:slim X2 insulin pump:

The t:slim X2 Insulin Delivery System has been our flagship technology solution. In February 2024, we expanded our pump portfolio

with the United States launch of Tandem Mobi. Both pumps feature our Control-IQ advanced hybrid closed loop technology, with an automated insulin delivery (AID) feature designed to help increase a user's time in targeted glycemic range. Our t:slim X2 and Tandem Mobi pumps can be used with a variety of infusion sets to offer patients choice in how and where their pump is worn. In addition, they are software-updatable from a personal computer and compatible with our web-based data management application.

46. That same day, the Company filed with the SEC a current report on Form 8-K, and attached to this Form 8-K was a press released headlined "Tandem Diabetes Care Announces Fourth Quarter and Full Year 2024 Financial Results and 2025 Financial Guidance," where the Company stated, in the relevant part:

#### About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ advanced hybrid closed-loop technology. Tandem Diabetes Care is headquartered in San Diego, California.

- 47. On February 27, 2025, the Company initiated a recall with the FDA of its t:slim X2 insulin pump with interoperable technology ("the February 2025 Recall"). The February 2025 Recall did not become public until it was published by the Company on August 7, 2025.
- 48. On April 30, 2025, the Company filed with the SEC its quarterly report on Form 10-Q for the period ended March 31, 2025 ("1Q2025 Report"). With respect to the t:slim X2 product, Defendants made the following statements:

The t:slim X2 was the first pump in the industry on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. This feature allows our t:slim X2 and Tandem Mobi customers to update their pump software independently. We believe this offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements

within their warranty cycle without having to purchase a new pump. These enhancements include new developments in our AID technology, CGM integrations and mobile app features. For example, we recently offered a pump software update to allow Tandem pump users access to the latest generation of our algorithm, Control-IQ+ technology, offering greater levels of personalization and flexibility within our algorithm.

- 49. Appended to the 1Q2025 Report as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants Sheridan and Vosseller, attesting that "[b]ased on my knowledge, this report [1Q2025 Report] does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."
- 50. The statements contained in ¶¶48 and 49 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the February 2025 Recall.
- 51. On May 23, 2025, the Company filed with the SEC a current report on Form 8-K, the Company made the following statements regarding its t:slim X2 product:

On May 21, 2025 (the "Effective Date"), Tandem Diabetes Care, Inc. (the "Company"), Tandem Diabetes Care Europe B.V. (with the Company, the "Company Entities"), F. Hoffmann-La Roche AG, Roche Diabetes Care GmbH, Roche Diabetes Care, Inc., Roche Diagnostics Operations Inc., Roche Diagnostics GmbH and Roche Diagnostics International AG (collectively, the "Roche Entities") entered into a Settlement, Mutual Release and Cross-License Agreement (the "Settlement Agreement") to resolve all actual or potential patent disputes as of the Effective Date relating to *the Company's t:slim X2 pump* and EP Patent No. 2 196 231 B1 (the '231 patent) and EP Patent No. 1 970 677 B1 (the '677 patent) (collectively, "Disputes"), including the pending patent infringement actions, revocation actions, counterclaims for revocation and actions for declaration of non-infringement of patents (collectively, the "Pending Actions") before local court divisions of the United Patent Court in France and Germany.

- 52. The statements contained in ¶51 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the February 2025 Recall.
- 53. On June 20, 2025, the Company issued a press release headlined "Tandem Diabetes Care Announces t:slim X2 Insulin Pump Compatibility with Abbott's FreeStyle Libre® 3 Plus Sensor in the United States," in the relevant part:

Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company today announced the Tandem t:slim X2 <sup>TM</sup> insulin pump with Control-IQ+ automated insulin delivery (AID) technology now works with Abbott's FreeStyle Libre® 3 Plus continuous glucose monitoring (CGM) sensor. The Company has initiated an early access program in the United States (U.S.), and intends to scale availability in the second half of 2025.

The t:slim X2 insulin pump is powered by Control-IQ+ technology, the latest generation of Tandem's advanced hybrid closed-loop algorithm, which adjusts insulin every 5 minutes based on predicted glucose values. It's the only system with the unique AutoBolus<sup>TM</sup> feature that calculates and delivers a correction bolus to help with missed meal boluses. Control-IQ+ is easy to start, use, and personalize, and this latest integration works with the FreeStyle Libre 3 Plus sensor and extends its benefits to even more people with diabetes.

"This is an exciting first step in our strategy to connect Tandem's portfolio of insulin pumps to Abbott's FreeStyle Libre 3 Plus sensors worldwide," said John Sheridan, president and chief executive officer of Tandem Diabetes Care. "We look forward to expanding access to our t:slim X2 users outside of the U.S. beginning later this year."

54. The statements contained in ¶53 were materially false and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the February 2025 Recall.

55. On August 6, 2025, the Company filed with the SEC a current report on Form 8-K. Attached to this Form 8-K was a press release in which the Company made statements regarding its t:slim X2 product:

Second Quarter 2025 Highlights

- Initiated an early access program for the t:slim X2<sup>TM</sup> insulin pump with Control-IQ+ technology integrated with Abbott's FreeStyle Libre® 3 Plus continuous glucose monitoring sensor in the U.S.
- Progressed multichannel initiative to include t:slim X2 supplies as a pharmacy benefit beginning in Q4 2025.
- 56. On the same day, the Company filed with the SEC its quarterly report on Form 10-Q for the period ended June 30, 2025 ("2Q2025 Report"). The Company made the following statements regarding its t:slim X2 product in the 2Q2025 Report:

The t:slim X2 was the first pump in the industry on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. This feature allows our customers to update their pump software independently. We believe this offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements within their warranty cycle without having to purchase a new pump. These enhancements generally include new developments in our AID technology, CGM integrations and mobile app features.

In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third parties with whom we work, that could contain vulnerabilities. . . . For example, in March 2024, we issued a recall of our Apple iOS t:connect mobile app in the United States relating to an issue that could cause rapid depletion of a user's t:slim X2 insulin pump battery (the March 2024 Recall). On August 20, 2024, we released an updated version of the impacted app to correct the issue described in the March 2024 recall.

57. Appended to the 2Q2025 Report as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants Sheridan and Vosseller, attesting that "[b]ased on my knowledge, this report [2Q2025 Report] does not contain any untrue statement of a material fact or omit to state a

material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

58. Also on August 6, 2025, after market hours, the Company held its Earnings Call for the period ended June 30, 2025 (the "2Q25 earnings call"). On the 2Q25 Earnings Call, Defendant Sheridan made the following statements regarding the Company's t:slim X2 product:

Our flagship pump, t:slim X2 continues to receive high customer satisfaction scores for its larger volume insulin reservoir, multiple sensor integrations and the convenience of having touchscreen control on the pump. In the second quarter, we announced t:slim's compatibility with Abbott's FreeStyle Libre 3 Plus sensor. Early access for this integration is now underway, and we plan to expand to full U.S. availability this fall, followed by launching internationally and integrating with Tandem Mobi.

Beginning in Q4, we plan to start selling t:slim supplies through the pharmacy channel to our eligible customer base. It's exciting evidence of our business transformation and important for our current t:slim customers as it can make pump therapy more affordable.

Turning to our international markets. The team delivered strong overall performance, driven by demand for t:slim, increasing pump renewals and growing supply sales. Commercial efforts are also underway to prepare for the launch of Tandem Mobi as we recently received CE Mark. We are now pursuing additional regulatory and pre-commercial activities such as securing in-country registrations and reimbursement. We are also continuing the rollout of the mobile app and Tandem Source that are prerequisites for Mobi's launch.

Last month, we initiated a field correction notice to inform t:slim users that we identified certain speaker versions that have higher-than-normal failure rates. We are taking necessary steps to address this issue, and there are no changes to our financial expectations as a result of this notification. We want you to be aware as we will be taking measures to aid customer awareness, such as issuing a press release.

- The statements contained in ¶55 through 58 were materially false 59. and/or misleading at the time they were made because Defendants recklessly disregarded the fact that Tandem's t:slim X2 product was subject to the February 2025 Recall.
- The statements contained in  $\P$  24, 26-31, 33, 35, 37, 38, 48, 49, 51, 60. 53, and 55-58 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the reliability of Tandem's t:slim X2 insulin pump was compromised by a systemic battery depletion defect linked to the t:connect mobile app; (2) the effectiveness and efficiency of Tandem's postmarket surveillance and quality systems were overstated; (3) the t:connect app and t:slim X2 speaker/software exhibited defects that caused pump shutdowns and rapid battery drain, placing patients at risk; and (4) as a result, Defendants' public statements were materially false and misleading at all relevant times.

## THE TRUTH BEGINS TO EMERGE

61. On August 12, 2024, before the market opened, the Company issued a press release headlined "Tandem Diabetes Care Provides Update on March 2024 Nationwide Recall of t:connect Mobile App for iOS Devices," in the relevant part:

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Tandem Diabetes Care, Inc. (Nasdaq: TNDM) today provided an update on the March 2024 recall of its Apple iOS t:connect mobile app in the United States relating to an issue that can cause rapid depletion of a user's t:slim X2 insulin pump battery. This battery depletion can result in the pump shutting down sooner than expected, which some customers have continued to experience following the release of version 2.7.1 of the app in March. Notices were emailed to impacted customers on August 9, 2024 with updated information and recommendations for helping avoid pump battery depletion. Tandem plans to release a new version of the app to

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address the remaining issues and will notify all users by email and app push notifications following its release.

Under-delivery of insulin because of a pump shutdown can result in hyperglycemia or diabetic ketoacidosis, which can be a life-threatening condition due to high blood sugar and lack of insulin. There have been 107 confirmed adverse events with this recall. Adverse events are defined as a confirmed high blood sugar and/or an event requiring medical intervention. Two hospitalizations and no deaths have been reported.

- 62. On this news, Tandem Diabetes stock fell \$2.8 per share, or 7.09%, to close at \$36.72 per share on August 12, 2024.
- 63. On August 7, 2025, before the market opened, the Company issued a press release headlined "Tandem Diabetes Care Issues Voluntary Medical Device Correction for Select t:slim X2 Insulin Pumps," in the relevant part:

Tandem Diabetes Care, Inc. (Nasdaq: TNDM) has announced a voluntary medical device correction for select t:slim X2 insulin pumps to address a potential speaker-related issue that can trigger an error resulting in a discontinuation of insulin delivery.

The error, which appears a Malfunction 16 alarm to the user, will stop insulin delivery and terminate communication between the insulin pump and the continuous glucose monitoring (CGM) device. If not addressed, this could result in hyperglycemia due to discontinuation of insulin delivery, real-time CGM Estimated Glucose Values, and CGM trends. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional. There have been 700 confirmed adverse events, defined as a confirmed high blood sugar and/or an event requiring medical intervention, and 59 reported injuries. No deaths have been reported.

Notices were sent directly to impacted customers in the United States (U.S.) between July 22 and 24, 2025 with instructions on what to do in the event of a Malfunction 16. A copy of this customer notification can be found at https://www.tandemdiabetes.com/docs/default-source/legal/company-update/malfunction-16-speaker-issue-tslimx2-qsf0024231.pdf.

More information, including a searchable list of serial numbers for impacted pumps can be found at tandemdiabetes.com/mal16-2025. The U.S. Food and Drug Administration and regulatory agencies outside of the U.S. have been notified of this action.

Tandem will be releasing a software update designed to enhance early detection of speaker failure. This update will also introduce persistent vibration alerts to help reduce potential safety risk. Tandem will notify all pump users when the software update becomes available and request that they complete the update of their insulin pump.

- 64. On this news, Tandem Diabetes stock fell \$2.87 per share, or 19.9%, to close at \$11.52 per share on August 7, 2025.
- 65. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

#### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

- 66. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired the Company's securities publicly traded on NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 67. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

- 68. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 69. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 70. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - whether the Exchange Act was violated by Defendants' acts as alleged herein;
  - whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of the Company;
  - whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
  - whether the Defendants caused the Company to issue false and misleading filings during the Class Period;
  - whether Defendants acted knowingly or recklessly in issuing false filings;
  - whether the prices of the Company securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 71. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 72. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
  - the Company's shares met the requirements for listing, and were listed and actively traded on NASDAQ, an efficient market;
  - as a public issuer, the Company filed periodic public reports;
  - the Company regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
  - the Company's securities were liquid and traded with moderate to heavy volume during the Class Period.
- 73. Based on the foregoing, the market for the Company's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 74. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute*

Citizens of the State of Utah v. United States, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

#### **COUNT I**

# For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder <u>Against All Defendants</u>

- 75. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 76. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- 77. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- 78. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:
  - employed devices, schemes and artifices to defraud;
  - made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
  - engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

- 79. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.
- 80. Individual Defendants, who are the senior officers of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or any other of the Company's personnel to members of the investing public, including Plaintiff and the Class.
- 81. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.
- 82. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated

by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

- 83. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.
- 84. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of the Company's securities during the Class Period.

#### **COUNT II**

# Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

- 85. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.
- 86. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's business practices.
- 87. As officers of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's' financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.
- 88. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various

reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

89. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

### PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

- (a) declaring this action to be a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating Plaintiff's counsel as Lead Counsel;
- (b) awarding damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, together with interest thereon;
- (c) awarding Plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) awarding Plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

## **JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

1	Dated: October, 2025	THE ROSEN LAW FIRM, P.A.
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